



Valvular heart disease  
Original research



## Early clinical and haemodynamic matched comparison of balloon-expandable valves

Jose R Delgado-Arana<sup>1</sup>, María X Gordillo-Monge<sup>2</sup>, Jonathan Halim<sup>3</sup>, Federico De Marco<sup>4</sup>, Carlo Trani<sup>5</sup>, Pedro Martin<sup>6</sup>, Fabio Infusino<sup>7</sup>, Marco Ancona<sup>8</sup>, Peter den Heijer<sup>3</sup>, Francesco Bedogni<sup>9</sup>, Luis Nombela Franco<sup>10, 11</sup>, Raul Moreno<sup>12</sup>, Gennaro Sargella<sup>7</sup>, Matteo Montorfano<sup>13</sup>, Cristhian Aristizabal-Duque<sup>1</sup>, Teresa Romero-Delgado<sup>2</sup>, Sandra Santos<sup>14</sup>, Alejandro Barrero<sup>15</sup>, Itziar Gomez Salvador<sup>16</sup>, Sander IJsselmuiden<sup>3</sup>, Alfredo Redondo Diéguez<sup>17, 18</sup>, José Alberto San Román Calvar<sup>19</sup>, Ignacio J Amat-Santos<sup>20</sup>

Correspondence to Dr Ignacio J Amat-Santos, Cardiology, University Clinic Hospital of Valladolid (3, Ramon y Cajal), Valladolid, 47005, Spain; [ijamat@gmail.com](mailto:ijamat@gmail.com)

### Abstract

**Objectives** The balloon-expandable Sapien-3 valve demonstrated superior results in terms of residual aortic regurgitation when compared with self-expandable devices. We aimed to compare for the first-time early outcomes of Sapien-3 transcatheter heart valve (THV) with the balloon-expandable Myval device.

**Methods** Consecutive real-world patients from nine European institutions with symptomatic severe aortic stenosis treated either with Sapien-3 or Myval THV devices after June 2018 were compared. Early clinical outcomes were prospectively gathered and blinded analysis of 30-day echocardiography was conducted. Matching for the following variables was performed: age, body surface area, Society of Thoracic Surgeons risk score, left ventricular function, mean gradient, transfemoral approach, aortic valvular calcium, aortic annulus mean diameter, area and eccentricity index.

**Results** A total of 416 patients treated either with the Sapien-3 (n=286, 68.7%) or with Myval THV (n=130, 31.3%) were included and 103 pairs compared after matching. Baseline characteristics were similar. Procedural success rate (Sapien-3: 94.2%; Myval: 93.2%, p=0.219), 30-day mortality (Sapien-3: 2.9%; Myval: 0.97%, p=0.625), clinical efficacy (12.6 vs 4.9%, p=0.057) and early safety (12.6 vs 4.9%, p=0.096) were comparable. There was a lower need for new permanent pacemaker (15.5 vs 5.8% p=0.020) with Myval. No significant differences were found in terms of moderate aortic regurgitation (1% for Sapien-3, 0% for Myval, p=0.314), but mean gradients were higher following Sapien-3 than after Myval (p<0.001).

**Conclusions** The new Myval balloon-expandable THV was favourable in terms of safety, with low rate of permanent pacemaker and with favourable residual gradients and paravalvular leak rate according to blinded echocardiographic analysis.

### Data availability statement

All data relevant to the study are included in the article or uploaded as supplementary information. All investigators have access to the database and the central pool of echocardiographic analysis. Due to research aims of monitoring all the information is available on request.

<https://doi.org/10.1136/heartjnl-2021-319349>

### Statistics from Altmetric.com



[See more details](#)

**BMJ | editage**

Let us guide you to publication success

Get expert editing and translation support with BMJ Author Services

[Get started](#)

### Request Permissions

If you wish to reuse any or all of this article please use the link below which will take you to the Copyright Clearance Center's RightsLink service. You will be able to get a quick price and instant permission to reuse the content in many different ways.

[Request permissions](#)

### Data availability statement

All data relevant to the study are included in the article or uploaded as supplementary information. All investigators have access to the database and the central pool of echocardiographic analysis. Due to research aims of monitoring all the information is available on request.

[View Full Text](#)

### Footnotes

**Twitter:** @drassantos, @qalexbarroMD, @Alfredo\_Redondo, @ignamatsant

**Contributors:** JRDA and IJAS designed the project, collected and analysed the information and wrote the final manuscript. MXGM,

JH, FDM, CT, PM, FI, MA, PdH, FB, LNF, RM, SS, MM, CA-D, TR-D, GS, AB, IGS, SI, ARD and JASRC helped to collect data, performed critical review and approved the final version of the manuscript.

**Funding:** The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

**Competing interests:** None declared.

**Provenance and peer review:** Not commissioned; internally peer reviewed.

**Supplemental material:** This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Read the full text or download the PDF:

Buy this article (£50)

Subscribe

Log in



**bmjcareers**

**Consultant Cardiac Surgeon**  
London | £99,532 to £131,964 per annum

We are recruiting a substantive Full Time Consultant Cardiac Surgeon to work alongside our existing cardiac surgeons

Recruiter: St George's University Hospitals NHS Foundation Trust

[Apply for this job](#)

---

**Senior Clinical Fellow in Cardiology**  
Bangor | £40,397 to £63,518 gross per annum pro rata

Applications are invited for the post of Senior Clinical Fellow to join the Betsi Cadwaladr University Health Board

Recruiter: Betsi Cadwaladr University Health Board

[Apply for this job](#)

---

**Consultant Cardiologist with interest in Imaging: MRI**  
Peterborough | £105,504 to £139,882 per annum

**Other content recommended for you**

Haemodynamic differences between two generations of a balloon-expandable transcatheter heart valve  
Nihal Wilde, *Heart*, 2022

Early versus newer generation devices for transcatheter aortic valve implantation in routine clinical practice: a propensity score matched analysis  
Thomas Pilgrim, *Open Heart*, 2018

Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients (SURTAVI Investigators) file, *Heart blog*, 2017

Clinical impact and evolution of mitral regurgitation following transcatheter aortic valve replacement: a meta-analysis  
Luis Nombela-Franco, Helene Eltchaninoff, Ralf Zahn, et al., *Heart*, 2015

Increased cardiovascular mortality in patients with mechanically expandable transcatheter aortic valve and without permanent pacemaker  
*Open Heart*, 2023

Powered by **TREND MD**



**CONTENT**

- Latest content
- Current issue
- Archive
- Browse by collection
- Most read articles
- Top cited articles
- Responses

**JOURNAL**

- About
- Editorial board
- Sign up for email alerts
- Subscribe
- Education in heart
- Best Research Paper Award
- Thank you to our reviewers

**AUTHORS**

- Instructions for authors
- Submit an article
- Editorial policies
- Open Access at BMJ
- BMJ Author Hub

**HELP**

- Contact us
- Reprints
- Permissions
- Advertising
- Feedback form



[Website Terms & Conditions](#)

[Privacy & Cookies](#)

[Contact BMJ](#)

[Cookie settings](#)

Online ISSN: 1468-201X    Print ISSN: 1355-6037

Copyright © 2024 BMJ Publishing Group Ltd & British Cardiovascular Society. All rights reserved.

**BMJ** **editage** Let BMJ Author Services guide you to publication success [Get started](#)



